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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 09/481,207      | 01/11/2000  | JEFFREY OWEN PHILLIPS | 40015630-003        | 5317             |

7590 02/01/2002

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EXAMINER

FAN, JANE T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1625

DATE MAILED: 02/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/481,207

Applicant(s)

PHILLIPS, JEFFREY OWEN

Examiner

Jane T. Fan

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 666,680,681,683,685,687-702,704,709-714,716,717 and 725 is/are allowed.
- 6) ☒ Claim(s) besides of item 5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 23.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 23, 27-35, 38-40, 42-43, 52-53, 65, 69, 73, 81, 84, 95-96, 104-110, 112-123, 127-135, 680-684, 729-746, 757-759, 765, 862-865 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is not clear how the weight ratio was derived for all PPI's and all kinds of "at least one buffer agent" and their combinations and permutations thereof. The specification does not have any antecedent basis or support for the newly claimed language.

3. Claims 95, 96, 104-110, 112-123, 127-135, 622, 624-650, 652-654, 656, 661, 718-719, 724, 757-759, 765, 866-867 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for omeprazole for hypersecretion only does not reasonably provide enablement for all PPI's for all "acid related" diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The following reasons apply:

1. "Acid related GI disorder " read on too little acid which is beyond the enablement.
2. It is not understood how can a solid composition be administered through a nasogastric or a gastric tube. It appears that the tube would be totally congested.

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3. For claim 622 and all dependent claims thereof, it is noted that the claimed language is not clear whether the composition is premixed ( prepared as a single dosage ) for administration or the administration is step-wise ( sequential) because in part (b) it is not able to monitor because it would be too difficult or too late to evaluate PH of a patient for proper treatment.
4. Claims 667, 679, 682, 684, 703 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 667 is a hybrid claim. The composition can not be prepared or shelved.

Claims 679, 682, 684 are improper because the term "comprising".

Claim 703 is confusing regarding the term " suspension tablet".

5. Claims 23 and all its dependent claims rejected under 35 U.S.C. 103(a) as being unpatentable over art of record for reasons of record. Moreover, in the patent law, that where patentability is based on a change of pH in a composition, such a change must be "critical". It must lead to a new and unexpected result. Applicants have the burden to prove such a criticality.
6. Claims 666, 680-681, 683, 685, 687-702, 704, 709-714, 716, 717, 725, 868 are allowable.
7. It is noted that two same copies of Japanese patent 05194224 are in the record. The second Japanese patent 05194225 is still not in the record. Applicants are requested to submit an English translation of JP 05194225. ( third request ).

#### CONCLUSION

Canceling all rejected claims, shortening the Abstract and submitting formal drawings would put this case for allowance.

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8 Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane T. Fan whose telephone number is 703-308-4705. The examiner can normally be reached on 7:00am-3:30pm, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4734 for regular communications and 703-308-4734 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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Jane T. Fan  
Primary Examiner  
Art Unit 1625

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January 31, 2002

A handwritten signature in black ink, appearing to read 'J. Fan', with a large, stylized loop for the 'J'.

**JANE FAN  
PRIMARY EXAMINER  
GROUP 1200**